Clinical drug trials bring new and more effective pharmacologic weapons to physicians almost on a daily basis. Most of these clinical studies that bring new drugs from bench to bedside are financed by pharmaceutical companies (sometimes referred to as Sponsors). Many of these drug trials are run by academic medical centers or by commercially oriented networks of contract-research organizations (CROs) and site-management organizations (SMOs). These clinical trials are generally governed by Master Clinical Research Agreements that the parties enter into. These agreements generally have strict confidentiality provisions.

The Food and Drug Administration (FDA) requires manufacturers to show that these products pass tests of efficacy and safety. To establish these efficacy and safety databases, clinical trials must be large, lengthy and conducted at multiple centers, because of a single site generally cannot recruit enough patients to ensure statistical validity.

Some trials have four layers of involved organizations (pharmaceutical manufacturer, CRO, SMO and physician-investigators). Furthermore, separate academic medical centers are joining together to form clinical research network joint ventures.

A clinical study’s raw data are generally stored centrally at the pharmaceutical company or at the CRO. Individual investigators may receive only portions of the data. Companies prefer to control or to retain control over the analysis of all of the data in large trials.

The subjects participating in a clinical trial generally sign Informed Consent forms before beginning treatment in the trial. These Informed Consent documents are covered by FDA regulations [20 CFR part 50] and generally do not place any confidentiality obligations on any of these treated subjects.

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3 Bodenheimer, page 1540.
4 Bodenheimer, page 1541.
5 Bodenheimer, page 1541.
I. GENERAL LEGAL PRINCIPLES REGARDING PUBLIC USE

A. Statutory Provisions

The U.S. Patent Laws contain two provisions [35 U.S.C. §102(a) and 102(b)] that relate to the public use bar to patentability.

The relevant portions of 35 U.S.C. §102(a) and §102(b) are as follows:

“A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country … before the invention thereof by the applicant for patent; or

(b) the invention was … in public use … more than one year prior to the date of the application for patent in the United States,”

B. Policy Interests

The underlying policy interests regarding the public use patentability bar are as follows: First, the public use bar prohibits the patenting if an inventor has forfeited or dedicated the invention as part of the public domain. In other words, if the inventor has forfeited or dedicated the invention to the public, the inventor may not remove the invention from the public domain. Secondly, if the public has detrimentally relied on the public nature of the invention, it should not be extracted from the public domain. In other words, if an inventor has forfeited or dedicated the invention to the public and more than one year has passed, the inventor cannot then remove the invention from the public domain and file a patent application to obtain a valid patent on that invention. Also, if the public has detrimentally relied on the public nature of the invention, it should not be extracted from the public domain.

As stated in the Continental Plastic case,

“The primary policy underlying the ‘public use’ case is that of detrimental public reliance, whereas the primary policy underlying an ‘on-sale’ case is that of prohibiting the commercial exploitation of the design beyond the statutorily prescribed time period.”

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7 See id., at 1079.
C. Public Use Tests

In *Egbert v. Lippmann*,\(^8\) the U.S. Supreme Court defined public use of an invention as:

“If an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, and it is so used, such use is public use, even though the use and knowledge of the use may be confined to one person.”

For the last decade, the Federal Circuit had developed a “totality of the circumstances” approach to evaluate both public use and on sale issues to patentability. Specifically, the Federal Circuit stated “… the court will want to consider the totality of circumstances relating to the character and extent of commercial activities, the type of invention and its state of development … along with the character and extent of bona fide experimentation”. *Western Marine Electronics, Inc. v. Furumo Electrical Company*, 764 F.2d 840, 845 (Fed. Cir. 1985). More specifically, the Federal Circuit said that courts must consider how the totality of the circumstances of the case comports with the policies underlying the public use bar. See *Manville Sales Corp. v. Paramount Systems, Inc.*, 16 USPQ 2d 1587, 1591 (Fed. Cir. 1990) and also *Tone Brothers Inc. v. Sysco Corp.*, 31 USPQ 2d 1321, 1324-1325 (Fed. Cir. 1994)

The Federal Circuit said evidence of experimentation is part of the totality of the circumstances to be considered in deciding whether a public use exists.\(^9\) That court also noted the following factors which should be in connection with the experimental use inquiry: (1) the length of the test period and number of tests as compared with a similar type of test on a similar type of design; (2) whether a user made any payment for the device; (3) whether a user agreed to use secretly; (4) whether records were kept of the progress of the test; and (5) whether persons other than the designer conducted the asserted experiments.\(^10\) See *Seal-Flex, Inc. v. Athletic Track & Coast Construction*, 98 F.3d 1318, 1323, n. 2 (Fed. Cir. 1996)

\(^8\) 104 U.S. 333, 336 (1881).
\(^9\) *Tone Brothers*, at 1325.
\(^10\) *Tone Brothers*, at 1326.
The U.S. Supreme Court rejected this totality of the circumstances in on sale cases, moving towards a rule-based approach in its analyses in *Pfaff v. Wells Electronics, Inc.*\(^{11}\) The Federal Circuit has now dropped the totality of the circumstances in line with the *Pfaff* decision for on sale cases.\(^{12}\)

One commentator\(^{13}\) proposes that the totality of the circumstances test be replaced in public use bar cases with a specific rule of law that is both an extension of the *Pfaff* approach and reinvigorates the historic distinction between public use and on sale issues. Professor White’s test for public use is as follows: (1) the invention must be dedicated to the public or there must be detrimental public reliance that the invention is in the public domain; and (2) the invention must be ready for patenting. Her test is very similar to the *Pfaff* test, replacing the first prong with the policies behind the public use bar. The second prong is the same as that in the *Pfaff* test.\(^{14}\)

Factors indicating whether or not a use has been dedicated to the public under this proposed test includes: (1) whether the invention is in general or universal use; (2) whether the inventor’s delay in filing, beyond the statutory period, has dedicated the invention to the public or allowed the public to have detrimentally relied that the invention is in the public domain; and (3) whether those skilled in the art have had access to the use. If those skilled in the art have had access to the use, this increases the likelihood of detrimental public reliance.\(^{15}\)

Under her proposed test, if an invention is still being experimented upon, it is not ready for its intended purposes. Thus, the issue of experimental use can be covered under the second prong of her proposed test: the invention must be ready for patenting.\(^{16}\)

**D. Meaning of “Public” in Public Use**

“Public” use means use of the product or process “in its natural and intended way” – even though the invention may in fact be hidden from public view with such use.\(^{17}\)

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\(^{11}\) The Court concluded that “the on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. Second, the invention must be ready for patenting. That condition may be satisfied in at least two ways: by proof of or reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.” 525 U.S. 55, 67-68 (1998).

\(^{12}\) See *Weatherchem Corp. v. J.L. Clark*, 49 USPQ 2d 1001, 1006 (Fed. Cir. 1998).


\(^{14}\) Id, at 434.

\(^{15}\) Id, at 458.

\(^{16}\) Id, at 437.

\(^{17}\) See *Lockwood v. American Airlines, Inc.*, 37 USPQ 2d 1534, 1535 (SD Calif. 1995), aff’d 107 F.3d 1565, 41USPQ 2d 1961 (Fed. Cir. 1997).
E. Secret Commercial Use of a Machine or Process By the Inventor

The commercial exploitation by the inventor of a machine or process constitutes a public use even though the machine or process is held secret.\(^\text{18}\)

F. In This Country

A public use bar under Section 102(b) occurs only if the use is “in this country”. However, an intentional delay in seeking a United States patent, coupled with a substantial period of commercial exploitation in foreign countries alone, may constitute abandonment under Section 102(c).\(^\text{19}\)

G. Experimental Use Doctrine

The experimental use doctrine provides that activity that would otherwise constitute the placing of an invention in “public use” will not trigger the Section 102(b) statutory bar if the use was incidental to experimentation. The leading case on experimental use is City of Elizabeth v. American Nicholson Pavement Co.\(^\text{20}\) The U.S. Supreme Court in Pfaff approved of this experimental use doctrine and the holding in the City of Elizabeth case:

“… an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention - - even if such testing occurs in the public eye. The law has long recognized the distinction between inventions put to experimental use and products sold commercially.”\(^\text{21}\)

H. Public Use Bars in Other Countries

Inventors who rely on the one-year Section 102(b) grace period after an initial use can endanger their patent rights in other countries that do not have this provision.

II. CLINICAL TRIALS CASE LAW

In International Tooth Crown Company v. Gaylord, 140 U.S. 55 (1891), the patentee put the invention in clinical use more than two years before filing a patent application and, thus, the U.S. Supreme Court said the patent was invalid. Where that use is mainly for purposes of trade and profit, and the experiments were merely incidental to that, the principal purpose and not the incident, must give character to the use. Also, the

\(^{18}\) See Metalizing Engineering Co. v. Kenyon Bearing Auto Parts Co., 153 F.2d 516, 68 USPQ 54 (2d Cir. 1946) cert. denied 328 U.S. 840, reh’g denied, 328 U.S. 881 (1946). Also see Chisum on Patents Section 6.02[5][b].

\(^{19}\) See Chisum on Patents – Sections 6.02[5][d] and 6.03.

\(^{20}\) 97 U.S. 126 (1877).

\(^{21}\) Pfaff, at page 64.
Supreme Court said that while a patentee has the right to test the durability of his invention as one of the elements of its success, those experiments should not extend, either in time or in the number of cases in which it is used, than is reasonably necessary for that purpose.

In *TP Laboratories v. Professional Positioners, Inc.*, 220 USPQ 577 (Fed. Cir. 1984), the patentee used the inventive orthodontic appliance on three patients more than one year prior to the filing date of the patent application. The Federal Circuit remanded the case to the district court after deciding that there should be a single inquiry into what is public use under Section 102(b) and evidence of experimental use should be included under that inquiry.

In *Pennwalt Corporation v. Akzona Inc, et al*, 222 USPQ 833 (1984), patentee attempted to show that its sales and uses were experimental, in accordance with a EPA temporary permit. The Federal Circuit held that a sale or use under a regulatory testing procedure does not make such uses or sales per se experimental for purposes of Section 102(b). The Federal Circuit also said a use or sale is experimental for purposes of Section 102(b) only if it represents a bona fide effort to perfect the invention or to ascertain whether it will answer its intended purpose.

In *Ethicon Inc. vs. United States Surgical Corp.*, 19 USPQ 2d 1721, 1790 (D. Conn. 1991) aff’d 965 F.2d 1065 (Fed. Cir. 1992), clinical tests by surgeon were deemed not a public use under Section 102(b).

**III. PUBLICATION PROVISIONS IN CLINICAL RESEARCH AGREEMENTS**

It is imperative that pharmaceutical and biotechnology companies (“Sponsors”) that engage universities and institutions to perform research and clinical studies take appropriate measures to best protect their confidential information and trade secrets. Since publication of confidential information may serve as a statutory bar to patent protection and result in loss of trade secret protection, particular focus must be paid to the publication clause of all research agreements.

Publication clauses should always provide the Sponsor with the prior opportunity to review and comment on any public disclosure (including any publication, poster session, abstract, manuscript and grant application) related to the research or study to: (1) afford the sponsor with an adequate opportunity to file patents on any patentable material that may be contained in the proposed publication, and (2) ensure compliance with the agreement’s confidentiality provisions by permitting removal of Sponsor’s trade secrets from the proposed publication.

**A. Protecting Patentable Inventions**

Also under Section 102(b), an inventor will be denied a patent if, more than twelve months before filing the patent application, the inventor disclosed the invention in
a printed publication in the United States or a foreign country. However, other countries may not grant the inventor this same grace period following publication for filing the patent application.

The Sponsor’s rights to review publications must extend to presentations because the delivery of a speech at an academic conference may constitute or result in a printed publication. In addition, the Sponsor should have the rights to review any manuscripts, abstracts, poster sessions and hand-outs for teaching purposes that relate to the research study, and any other dissemination of the invention that may be accessible to the public, including information that may be accessible to the public through the Freedom of Information Act, such as grant proposals. Since dedication of an invention to the public is the basis for the publication bar of Section 102(b), disclosure of the knowledge of an invention to another without securing a commitment of confidentiality may be considered dissemination of the invention to the public because the inventor no longer controls the knowledge of the invention.

The Sponsor should request a copy of the patent and publication policies of the university or institution and thoroughly consider the impact such policies may have on the agreement’s confidentiality and publication provisions; particularly if the agreement is “subject to” such policies. Reasonable patent policies generally provide for a short delay in the publication of research results for patenting purposes and the Sponsor’s review of confidential information, but the university will be reluctant to agree to any provision that permits suppression of the publication or the Sponsor’s right to impose substantive changes in the publication.

B. Protecting Trade Secrets

Finally, the Sponsor should take all appropriate measures to limit public disclosure of its trade secrets and proprietary information, including clinical data, by: (a) limiting access to only those investigators who have a need to know; (b) discussing confidentiality at the outset with each clinical investigator; (c) requiring that each investigator sign a confidentiality agreement or ensuring that each investigator have a written agreement with the university or institution; (d) prohibiting the photocopying of proprietary documents, including, except to the extent necessary to conduct the study, study data; (e) monitoring access by maintaining logs of the nature and scope of disclosure; (f) limiting the scope of proprietary information to only that information that is necessary for the individual investigator or researcher to perform the contract services; and (g) marking documents as “proprietary” or “confidential”.

A well-drafted publication clause will strike a fair balance between the Sponsor’s interest in protecting its patentable information and trade secrets and the university’s general commitment to openness in research and publication of results.